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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/998,667	12/03/2001	Esteban Masuda	021044-000600US	7585

20350 7590 05/01/2003

TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER

GIBBS, TERRA C

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/01/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/998,667

Applicant(s)

MASUDA ET AL.

Examiner

Terra C. Gibbs

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 March 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-43 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other _____

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DETAILED ACTION

The Sequence Amendment and Amendment to claims 24 and 33 is acknowledged.

Claims 1-46 are pending in the instant application.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-23, drawn to a method for identifying a compound that modulates T lymphocyte activation, *in vivo*, classifiable in class 435, subclass 375 .
- II. Claims 1-23, drawn to a method for identifying a compound that modulates T lymphocyte activation, *in vitro*, classifiable in class 435, subclass 375.
- III. Claims 24-32, drawn to a method for identifying a compound capable of interfering with binding of a TRAC1 polypeptide or a fragment thereof, *in vivo*, classifiable in class 435, subclass 7.2.
- IV. Claims 24-32, drawn to a method for identifying a compound capable of interfering with binding of a TRAC1 polypeptide or a fragment thereof, *in vitro*, classifiable in class 435, subclass 7.2.
- V. Claims 33 and 34, drawn to an isolated complex comprising a TRAC1 polypeptide or fragment thereof bound to an E2 ubiquitin-conjugating enzyme polypeptide, classifiable in class 530, subclass 300 .

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- VI. Claims 35, 36, 37 and 42, drawn to a method of modulating T lymphocyte activation in a subject comprising the administration of an antibody, classifiable in class 424, subclass 130.1.
- VII. Claims 35 and 38, drawn to a method of modulating T lymphocyte activation in a subject comprising the administration of an antisense molecule, classifiable in class 514, subclass 44.
- VIII. Claims 35 and 29, drawn to a method of modulating T lymphocyte activation in a subject comprising the administration of a small organic molecule, classifiable in class 514, subclass 4.
- IX. Claims 35, 40, and 41, drawn to a method of modulating T lymphocyte activation in a subject comprising the administration of a peptide, classifiable in class 514, subclass 2.
- X. Claims 43 and 44, drawn to method of modulating T lymphocyte activation in a subject comprising the administration of a polypeptide of SEQ ID NO: 1, classifiable in class 514, subclass 2.
- XI. Claims 45 and 46, drawn to a method of modulating T lymphocyte activation in a subject comprising the administration of nucleic acid encoding a TRAC1 polypeptide, classifiable in class 514, subclass 4.

The inventions are distinct, each from the other because of the following reasons:

Although the methods of Groups I and II are related because they encompass a method for identifying a compound that modulates T lymphocyte activation, they are patentably distinct

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from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: Group I is conducted *in vivo* and Group II is conducted *in vitro* so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method for identifying a compound that modulates T lymphocyte activation, *in vivo* of Group I could would not encompass all of the art relevant to the method for identifying a compound that modulates T lymphocyte activation, *in vitro* of Group II, since the *in vivo* method would encompass a search for gene therapy which is not encompassed in the *in vitro* method. They are materially distinct methods which differ in method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Thus, they are patentably distinct from each other.

Although the methods of Groups II and III are related because they encompass a method for identifying a compound capable of interfering with binding of TRAC1 polypeptide or a fragment thereof, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: Group III is conducted *in vivo* and Group IV is conducted *in vitro* so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the encompass a method for identifying a compound capable of interfering with binding of TRAC1 polypeptide or a fragment thereof, *in vivo* of Group III would not encompass all of the art relevant to the

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encompass a method for identifying a compound capable of interfering with binding of TRAC1 polypeptide or a fragment thereof, *in vitro* of Group IV, since the *in vivo* method would encompass a search for gene therapy which is not encompassed in the *in vitro* method. They are materially distinct methods which differ in method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Thus, they are patentably distinct from each other.

Inventions of Group V and Groups III and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the isolated complex comprising a TRAC1 polypeptide or fragment thereof bound to an E2 ubiquitin-conjugating enzyme polypeptide can be used as an antibody to identify TRAC1 protein expression, which is a materially different process than a method for identifying a compound capable of interfering with binding of TRAC1 polypeptide or a fragment thereof.

Inventions of Groups VI-IX are unrelated, each from the other. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the inventions of Groups VI-IX are unrelated and distinct because they are different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the antibody of Group VI would not encompass all of the art relevant to the

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antisense molecule of Group VII. Likewise, a search of the small organic molecule of Group VIII would not encompass all of the art relevant to the peptide of group IX. The differences between Inventions VI-IX are further underscored by their different classifications and independent search status. Thus, they are unrelated and patentably distinct from each other.

Although the methods of Groups X and XI are related because they encompass a method for modulating T lymphocyte activation in a subject, they are patentably distinct from each other. Although there are no provisions under the section for "Relationship of Inventions" in MPEP 806.05 for inventive groups that are directed to related methods, restriction is deemed to be proper because these methods constitute patentably distinct inventions for the following reasons: They employ different molecules with different chemical and physical structures so that independent searches of the prior art would be required that would constitute a serious burden on the Examiner. For example, a search of the method of modulating T lymphocyte activation in a subject comprising the administration of a polypeptide of Group X would not encompass all of the art relevant to the method of modulating T lymphocyte activation in a subject comprising the administration of a nucleic acid encoding a TRAC1 polypeptide of Group XI. They are materially distinct methods which differ in method steps, reagents and/or dosages and/or schedules used, response variables, and criteria for success. Thus, they are patentably distinct from each other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

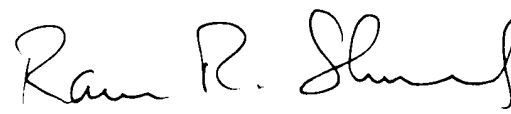
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Terra C. Gibbs whose telephone number is (703) 306-3221. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John L. LeGuyader can be reached on (703) 308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 746-8693 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

tcg
April 23, 2003


RAM SHUKLA
PRIMARY EXAMINER